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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|---|-------------|----------------------|---------------------|------------------|--|--|
| 10/591,421 | 09/01/2006 | Nobuhiko Fushimi | Q96479 | 3051 | | |
| 23373 7590 66242009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. | | | EXAM | EXAMINER | | |
| | | | HENRY, M | HENRY, MICHAEL C | | |
| SUITE 800 WASHINGTON, DC 20037 | | ART UNIT | PAPER NUMBER | | | |
| | , | | 1623 | | | |
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| | | | 06/24/2009 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

| Application No. | Applicant(s) | | | | |
|------------------|----------------|--|--|--|--|
| 10/591,421 | FUSHIMI ET AL. | | | | |
| Examiner | Art Unit | | | | |
| MICHAEL C. HENRY | 1623 | | | | |

| - | Examiner | ALC OTHE | | | | |
|--|---|--|-------------|--|--|--|
| | MICHAEL C. HENRY | 1623 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D/ - Extensions of time may be available under the provisions of 37 CFR 1.1: A William of More | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a repty be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this o D (35 U.S.C. § 133). | , | | | |
| Status | | | | | | |
| 1)☐ Responsive to communication(s) filed on | action is non-final. nce except for formal matters, pro | | e merits is | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-22.27-31 and 35 is/are pending in the 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are eljected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-22.27-31.35 are subject to restriction | wn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | epted or b) objected to by the lidrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | a 37 CFR 1.85(a). jected to. See 37 C | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)). | on No ed in this National | Stage | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |

| Notice of References Cited (PTO-892) | 4) |
|--|----|
| Notice of Draftsperson's Patent Drawing Review (PTO-948) | - |
| 2) The formation Blood ourse Chateman and (BTS/CE from) | 5) |

Notice of Informal Patent Application 6) Other:

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date _____

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Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claim(s) 1-18, 27-28, 35, drawn a fused heterocyclic derivative represented by a given general formula (I).
 - Group II, claim(s) 19-22, 29-31 drawn to a method for the inhibition of postprandial hyperglycemia, which comprises administering an effective amount of a fused heterocyclic derivative of said formula.
- 2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature linking the groups appears to be that they all relate to a fused heterocyclic derivative represented by a given general formula (I) and the use the fused heterocyclic derivative for the inhibition of postprandial hyperglycemia.
- 3. The technical feature linking groups I-II appears to be that they all relate to a fused heterocyclic derivative represented by a given general formula (I) and the use the fused heterocyclic derivative for the inhibition of postprandial hyperglycemia.
- However, Ellsworth et al.(WO 01/27128 A1) describes a SGLT2 inhibitors or heterocyclic derivative composition and their use for the treatment of said for treating

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diabetes which involves inhibition of hyperglycemia (see abstract and claims). The prior art compounds are therefore made and used for the treatment of the same diseases, as those instantly claimed.

5. Therefore, the special technical feature linking the inventions of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a fused heterocyclic derivative represented by a given general formula (I).

The special technical feature of Group II is considered to be a method for the inhibition of postpariandial hyperglycemia, which comprises administering an effective amount of a fused heterocyclic derivative of said formula (1).

6. Claims 1-22, 27-31, 35 are generic to the following disclosed patentably distinct species: For example the compounds in claim 1 which distinctly have inhibitors of different or distinct structures such as the compound with thienyl group as opposed to imidazole. The species are independent or distinct because are classified differently. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an Application/Control Number: 10/591,421

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allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

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Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry June 19, 2009. /Shaojia Anna Jiang/ Supervisory Patent Examiner Art Unit 1623